

REMARKS

Independent claims 20 and 21 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Geisser (U.S. Patent No. 5,454,815) in view of Merrill (U.S. Pub. No. 2003/0119935). Claims 12, 13, and 15-19 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Geisser in view of Merrill further in view of Judd (U.S. Patent No. 1,396,934). The Applicants respectfully disagree with the rejections.

As a result, the undersigned attorney for the Applicants spoke with the Examiner by telephone on Monday, April 28, 2008. The undersigned pointed out that Merrill did not disclose what was claimed because the reference teaches that a prosthetic made according to the teachings of Merrill is capable of being sterilized by standard means, including heat sterilization. In contrast, the claims of the subject application are directed to a rasp made of a plastic material that deteriorates at heat sterilization temperatures. It was also pointed out that there is a difference in the UHMWPE as a raw material, and radiation treated UHMWPE. The Examiner seemed to understand this position and agreed that the relevance of Merrill to the pending claims may be in question. However, the Examiner expressed some reservation about the scope of the independent claim (claim 21) and suggested that a further amendment might further distinguish the cited reference. Accordingly, Applicants have amended the claim to recite further that the rasp wears out after a single use. Support for this amendment may be found in the specification at page 2, lines 17-21. This feature assures that the rasp is not reused, and this feature is not taught in any of the references.

Expanding on the above summary, it was asserted in the Office Action that

Geisser discloses a device comprising protrusions, i.e. teeth, made of a plastic material, for example polyethylene, which is to come into contact with the part of bone and rasp it from the remaining bone, wherein the plastic is hard enough to remove the bone. Geisser discloses the device is intended to be use[d] once and will not require cleaning or sterilization after use (column 1 lines 61-62). Geisser fails to disclose the device being manufactured from a plastic capable of deteriorating when placed in an autoclave at a temperature of at least 137 degrees Celsius.

In view of the amendment to claim 21, Geisser fails to disclose a rasp that wears out after a single use. Geisser teaches that its rasp may be manufactured inexpensively, and therefore multiple use of the rasp can be avoided. Col. 1, lines 60-61. Geisser also teaches that an inexpensive rasp

may be discarded after a single use and therefore cleaning or sterilizing the rasp is unnecessary. Col. 1, lines 61-63. But, Geisser does not teach that the rasp wears out after a single use so that it may not be used a second time.

With respect to Geisser's failure to disclose the device being manufactured from a plastic capable of deteriorating at autoclave temperatures, it was asserted by the Examiner that Merrill teaches the claimed limitations:

Merrill teaches a device comprised of a radiation treated ultra high molecular weight polyethylene, which can be treated with gamma radiation (page 1 paragraph 10), that has a melting point of 137 degrees Celsius (page 4 paragraph 09). It would have been obvious to one having ordinary skill in the art at the time the invention was made to manufacture the device of Geisser wherein the device is manufactured from a radiation treated ultra high molecular weight polyethylene in view of Merrill in order to improve the wear resistance of the device.

The Applicants respectfully disagree. The cited references would not provide a reasonable expectation of success in creating the claimed invention of the subject application because Merrill explicitly states that a prosthetic made with radiation treated UHMWPE is capable of heat sterilization (i.e., autoclaving).

A desired feature of the claimed rasp is that it may only be used once – and this feature is at least partially achieved by the fact that the rasp deteriorates if one attempts to sterilize the rasp in an autoclave. Paragraph 42 of Merrill explicitly teaches that the disclosed prostheses are capable of being sterilized by heat (which would include use of an autoclave, a standard means for sterilizing):

[0042] The prostheses of this invention are non-toxic to humans. They are not subject to deterioration by normal body constituents, e.g., blood or interstitial fluids. They are capable of being sterilized by standard means, including, e.g., heat or ethylene oxide.

Thus, one who sought to achieve one of the objects of the claimed invention of the subject application would not be motivated to use the materials disclosed in Merrill. There would be no expectation of success in creating a rasp that deteriorates in an autoclave, because Merrill teaches that the disclosed prostheses are capable of being sterilized by heating.

That the prostheses of Merrill will not deteriorate during heat sterilization is not contradicted by the reference's teachings about "melting peaks." At paragraph 51, Merrill discusses various melting peak temperatures for UHMWPE. UHMWPE is defined, at paragraph 43 as the ethylene polymers *before any treatment*:

[0043] By UHMWPE is meant linear non-branched chains of ethylene that have molecular weights in excess of about

500,000, preferably above about 1,000,000, and more preferably above about 2,000,000. Often the molecular weights can be at least as high as about 8,000,000. By initial average molecular weight is meant the average molecular weight of the UHMWPE starting material, prior to any irradiation.

In contrast, the radiation treated UHMWPE is defined at paragraph 46 as the UHMWPE that has been treated with radiation:

[0046] By radiation treated UHMWPE is meant UHMWPE which has been treated with radiation, e.g., gamma radiation or electron radiation, so as to induce cross-links between the polymeric chains of the UHMWPE.

Again, the prostheses disclosed in Merrill are made of "radiation treated ultra high molecular weight polyethylene (UHMWPE)..." Paragraph 10. The radiation treated (cross-linked) polyethylene product would not have the same physical properties, including melting point, as UHMWPE. Radiation treated UHMWPE was used because of its superior properties, including its capability of being sterilized by heat. Paragraph 42.

Moreover, Merrill discloses prostheses in which a sliding surface is formed between a load bearing surface made of radiation treated UHMWPE and a metal or ceramic countersurface. Paragraph 36. In such a configuration, there will be less friction between the two materials, resulting in a lesser production of fine particles between them and a longer life of the prosthesis. The disclosed radiation treated UHMWPE, then, reduces wear between the materials. This is exactly the opposite from the claimed invention, where a hardness differential is required, and where the rasp must be harder than the bone so as to rasp part of the bone from the bone. Thus, one would not be motivated to select the materials disclosed in Merrill.

Since the combination of Geisser and Merrill does not disclose the claimed rasp, the references certainly do not "disclose a device inherently capable of being [made] by" the claimed method.

Therefore, the Applicants believe claims 20 and 21 are in condition for allowance. Since the independent claims are believed in allowable form, the claims dependent therefrom are also believed in allowable form. In any event, the Applicants believe that at least some of the dependent claims are patentable over the cited references of their own merit.

For example, with respect to claims 15 and 16, it is asserted by the Examiner that Judd "teaches a device comprising a plastic body comprising

a metallic insert fully embedded in the plastic material in order to reinforce the plastic material." The Applicants assert that Judd is non-analogous art (it teaches a toilet (closet) seat fixture) because Judd (1) does not relate to the bone-rasping art area and (2) is not pertinent to the problem of providing either a cutting and reinforcing insert or a reinforcing insert to a rasp used to rasp part of a bone from the bone. Simply stated, one would not look to the toilet seat art to solve a problem in the prosthesis art.

Also, new independent claims 22-24 have been added.

Applicants believe these new claims are also patentable over the cited prior art for at least the reason that the cited prior art does not teach a cutting guide ancillary or acetabulum drill that wears out after a single use, or a method for manufacturing the same. A check in the amount of \$210.00 is enclosed for the two (2) independent claims in excess of the three (3) claims previously paid for. If any further fee is required, the Commissioner is hereby authorized to charge payment of any additional fees associated with this communication or credit any overpayment to Deposit Account No. 18-0987.

In view of the foregoing, the Applicants respectfully request the issuance of a Notice of Allowance for claims 12, 13, 15-21, and 22-24. If any issues remain, a telephone call to the undersigned would be appreciated.

Respectfully submitted,



Edward G. Greive, Reg. No. 24,726
Renner, Kenner, Greive, Bobak, Taylor & Weber
Fourth Floor, First National Tower
Akron, Ohio 44308-1456
Telephone: (330) 376-1242

Attorney for Applicants

August 4, 2008